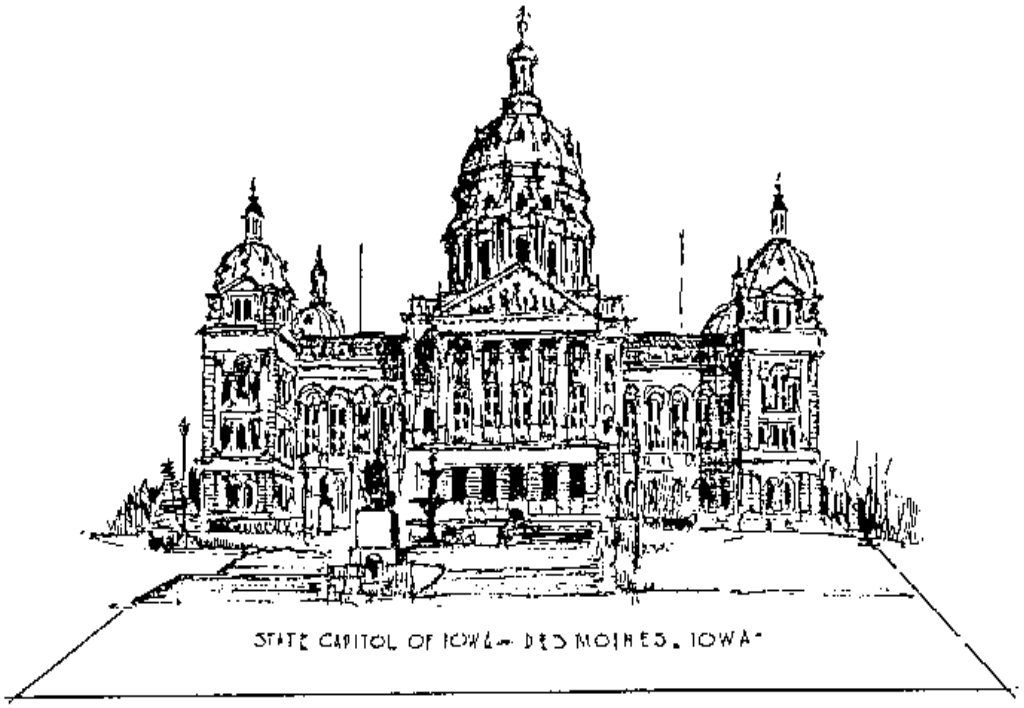
IOWA DEPARTMENT OF PUBLIC HEALTH

LOW, MEDIUM, AND HIGH DOSE-RATE REMOTE DEVICES REGULATORY GUIDE



Iowa Department of Public Health
Bureau of Radiological Health
Radioactive Materials Section
Lucas State Office Building, 5th Floor
321 East 12th Street
Des Moines, Iowa 50319-0075

IDPH REGULATORY GUIDE FOR LOW, MEDIUM, AND HIGH DOSE-RATE REMOTE DEVICES

1. INTRODUCTION

1.1 GENERAL

The Iowa Department of Public Health (IDPH) regulates the intentional internal or external administration of by-product material or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Iowa Radiation Machines and Radioactive Materials Rules, Chapter 641-41.2

The IDPH usually issues a single by-product material license to cover the radioisotope program. However, separate licenses must be obtained for the following:

- gamma stereotactic radiosurgery devices (gamma knives)
- high, medium, and low dose rate afterloaders
- irradiators
- nuclear powered pacemakers
- teletherapy devices

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the regulations identified in Chapter 641-41.2 and should then complete the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.1.1 PURPOSE OF GUIDE

This guide is designed to describe the type and extent of information needed by the IDPH to evaluate an application for use of low, medium, and high dose-rate devices. It also describes the by-product material regulations for their use.

1.2 APPLICABLE REGULATIONS

In addition to 641-41.2, other regulations pertaining to the medical use of by-product material found in Chapters 38, 39, and 40 of the Radiation Machines and Radioactive Materials Rules. You may go to www.idph.state.ia.us and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...In addition to complying with the requirements set forth in this Chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing an Application for Radioactive Materials License. You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All typed papers, sketches, and drawings, should be on 8 1/2 x 11-inch paper to facilitate handling and review, if possible. If larger drawings are necessary, fold them to 8 1/2 x 11 inches.

You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the public in the IDPH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of propriety information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. Submit only the training and experience of individuals demonstrating their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Submit dates of birth, social security numbers, and radiation dose information only if specifically requested by IDPH.

Retain a copy of your application. The license incorporates the statements, representations, and supplements in your application as well as the requirements in the regulations. Statements and representations in the application or supporting documentation become enforceable as if they were regulations.

3. DEFINITIONS

This guidance defines the following terms as:

- ***High dose-rate (HDR)*** -- a dose rate of 20 or more centigray (rads) per minute.
- ***Medium dose-rate (MDR)*** -- a dose rate between 200 centigray (rads) per hour and 20 centigray (rads) per minute.
- ***Low dose-rate (LDR)*** -- a dose rate of 4 to 200 centigray (rads) per hour.
- ***Pulsed dose-rate afterloader (PDR)*** -- a special type of remote afterloading device that uses a single source capable of delivering dose rates in the “high dose rate” range, but is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour. Based solely on their instantaneous exposure rate, these devices are treated the same as high dose-rate devices in this document.

4. CONTENT OF APPLICATION

This portion of the guide explains, item by item, the information requested on an IDPH application. The appendices to this guide serve to provide additional information on certain subject areas. To provide a model procedure the applicant may adopt in response to an item on the application form, or to provide an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, or call 515-281-3478.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same address at which the material will be used as specified in Item 1.b.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. If by-product material used at more than one location, specify the address of each location. In items 6 through 12 of the application, describe the intended use, the facilities, and equipment at each location.

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO or President with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee if the CEO or President provides that authorization in writing to IDPH.

The IDPH recognizes that licensees may use a consulting service to help prepare the license application and provide support to the radiation safety program. However, if you choose to have the consultant the point of contact for any IDPH questions, we remind you that the licensee management is ultimately responsible for all aspects of the program. This includes any services performed by the consulting service.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS -- TRAINING AND EXPERIENCE

Responsible individuals are the authorized users and the RSO. 641-39.4(25) requires that a qualified applicant have training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. 641-41.2(73), (74) and (75) provides specific criteria for training and experience for authorized users and RSO. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

4.1. -- AUTHORIZED USERS FOR MEDICAL USE

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate,
2. Prescription of the radiation dosage,
3. Actual use or direction of technologists or other paramedical personnel in the use of by-product material, and
4. Evaluation of therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the direct supervision of an authorized user. Technologists or other personnel may use by-product material under an authorized user's supervision when permitted under Chapter 42. Supervision is defined in 641-41.2(11).

A. Provide the full name of each individual user and note, by reference to Item 6, which proposed uses are requested for the individual.

B. If a physician previously authorized for medical use wishes to use material permitted by the previous Iowa Department of Public Health license, submit the previous license number. You should submit a copy of the license on which the physician was named as an authorized user if any other Agreement State or the US NRC issued the license.

C. If a physician is certified by an organization listed in the appropriate section of 641-41.2(73), submit the "*Medical Use Training and Experience and Preceptor Attestation"* along with a copy of the specialty board certificate indicating that the physician is “AU Eligible”.

D. Physicians not previously authorized by NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using the "*Medical Use Training and Experience and Preceptor Attestation".* This documentation will be reviewed on a case-by-case basis..

E. All training and experience shall have been obtained within the seven years preceding the date of application or the individual must submit verification of continuing applicable experience since the required training and experience was completed. See 41.2(77).

4.2. – AUTHORIZED PHYSICIST

A. Submit a copy of the NRC or Agreement State license on which the physicist is authorized as either a teletherapy or a brachytherapy physicist.

B. If the license is of limited scope, you should submit information verifying that the proposed authorized physicist meets the requirements of 641-41.2(74).

C. If license is a broad scope, you should state that the Radiation Safety Committee will approve users for the device(s) who are physicists who meet requirements specified in 641-41.2(74).

4.3 -- SUPERVISION

Authorized user supervision requirements are outlined in 641-41.2(11).

Remote afterloading devices are sophisticated in design and capable of delivering an extremely high dose in a relatively short time. Considering this, the IDPH requires that the radiation physicist be physically present during patient treatment. To provide the technical expertise needed in the case of equipment failure. Verify that the radiation physicist will be present during patient treatment.

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the

individual's training and experience using Supplement A. Even if the licensee employs a consultant as RSO, the licensee is still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner.

ITEM 6. -- RADIOACTIVE MATERIAL

A. SOURCE DESCRIPTION

If you wish to possess and use more than one radionuclide in the device, provide the following information for each radionuclide:

1. Radionuclide.

2. Manufacturer's name and model number.

3. Maximum activity per device. The activity may not exceed the activity specified by the manufacturer for the specific device and source combination.

4. Maximum number of sources to be possessed at any one time. You may wish to request two sources (or sets of sources). One set used in the device and the other stored in its shipping container. If more than one source model is referenced in item 2, you should indicate the maximum number of sources requested of each model number.

5. If applicable, you should request authorization for possession of depleted uranium in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange. Review and indicate the manufacturer's specifications for each device to determine the total quantity of depleted uranium present in the device in units of kilograms. Indicate whether depleted uranium is used for shielding the source(s) within the device.

B. DEVICE DESCRIPTION

1. Specify the manufacturer's name, address, and telephone number for each device requested, and

2. Indicate the model name and/or number and serial number for each device requested.

ITEM 7. -- PURPOSE

You should specify the uses or types of treatment planned for the device (e.g., for interstitial and/or intracavitary treatment of cancer in humans). Any other intended uses, such as intraluminal, intraoperative, or non-human use (e.g., physics calibrations or medical research, etc.) should be described so that the intended uses are apparent to the IDPH review staff.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program.

ITEM 9. -- TRAINING FOR INDIVIDUALS

A. Submit outlines of initial training that you give to authorized physician-users and device operators. Include a description of the didactic portion of the training and the minimum hours of "hands on" device operation training that will be provided. The training should be no less than eight (8) hours. Training should be specific to the device model, and include the following:

   1. Radiation protection and instrumentation, including the proper use of personnel dosimeters, survey instruments, and radiation monitors.

   2. The operating and emergency procedures.

   3. Design, use and function of the device, including safety systems.

   4. On-the-job training in actual operation of the device under the direct supervision of an experience device user. This aspect of the training should include "dry runs" (using dummy sources) of routine patient set-up and treatment, as well as implementation of your emergency procedures.

   5. Method of determining each trainee's competency to use the device for each type of proposed use.

B. Submit the name, affiliation, and qualifications of the instructor(s) conducting the training. A description of the trainer's experience in use of the specific device(s) for which training will be provided should also be included.

C. An outline of the topics to be covered during periodic retraining of device operators should be submitted and you should confirm that retraining will be conducted at intervals not to exceed 12 months. You should also confirm that retraining will include practice in implementing (using dummy sources) that licensee's emergency procedures (dry run).

D. You should submit a description of the orientation training that will be provided to ancillary staff (including nurses, technologists, security staff, custodians, etc.) that provide patient care during treatment or frequent areas where remote afterloading devices are used or stored. This training should meet the requirements of 641.40.111(136C) and 641-41.2(44). You should confirm that the staff will be provided refresher training, as appropriate, at intervals not to exceed 12 months. An outline of the training for ancillary personnel should be submitted for review.

E. Training provided to nursing personnel caring for patients undergoing a low dose rate treatment that is performed in a patient room should be consistent with 641-41.2(44). In addition, you should confirm that nursing personnel will be provided training in the proper use of a survey instrument if patient care requires that nursing personnel work in close proximity to the patient. Alternatively, you should confirm that an individual trained in the use of a survey instrument and the procedures specified in 641.41.2(44) will be present during periods when patient care is performed.

F. Confirm that records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. Such records should include the names of the instructors, the names of attendees, and an outline of the topics discussed.

ITEM 10. -- FACILITIES AND EQUIPMENT

A. Submit annotated drawings of each dedicated treatment room indicating:

   1. Scale, plan and elevation.

   2. Identification of the room(s), including room number(s).

3. Type, density and thickness of all shielding materials, including walls, floor and ceiling.

4. The location of the gamma stereotactic unit within the room. Distances from the isotope center of the device should be included.

5. Location of doors, windows, conduits, etc.

6. Distance to and the nature of use for adjacent areas with indication of whether the areas are restricted or unrestricted, as defined in Chapter 38 of the Iowa Department of Public Health's Radiation Machines and Radioactive Materials Rules.

NOTE: The information provided should be sufficient to enable IDPH staff to conduct an independent review of the shielding design. To that end, distances from the source center should be referenced.

Treatments must be performed in rooms specially constructed or modified. The use of afterloading devices must be restricted to the specific room described in your application. Relocation of a device to another area of use requires prior IDPH approval.

B. If you request authorization to use a low dose-rate afterloading device in multiple rooms rather than in a dedicated room, the following information should be submitted:

1. Confirm that when portable shields are required to obtain compliance with 641-40.26(136C), a positive method are correctly positioned for each treatment (such as permanent position markings or electrical/mechanical shield interlocks) of ensuring that the shield(s) will be employed.

2. Confirm that promptly after initiating treatment; surveys of restricted and unrestricted areas contiguous with the treatment room will be conducted to demonstrate compliance with Chapter 40 exposure limits.

3. Confirm that records of the surveys described above will be maintained for a period of three years and that such records will include:

a. An annotated drawing of the room used for treatment (showing the configuration of the portable shields relative to the patient, if applicable)

b. The measured dose rate at several points in contiguous restricted and unrestricted areas

c. The make, model and serial number of the instrument used to make the survey; and

d. The initials of the individual who made the survey.

4. You should confirm that after relocating a device to a new location, and before treatment, all safety features and interlocks are operating properly.

NOTE: Low dose-rate devices may be licensed for use in multiple rooms within a single building provided that portable shields are used to obtain compliance with the dose limits for unrestricted areas adjacent to the treatment room (patient room).

C. You should equip each dedicated treatment room for high and medium dose-rate devices with continuous viewing and intercom systems to allow for patient observation during treatment. A description of the systems should be provided with the application and should include:

1. The primary intercom and viewing systems.

2. Backup systems to be used if the primary systems fail. Alternatively, you should commit to suspend treatments until the primary system is repaired.

For patient rooms where treatment using a low dose-rate afterloading device is planned, you should describe how

- the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment, and

- how to provide for prompt detection of any operational problems with the afterloading device during treatment.

D. Provide a description of the security to be provided for each room where a remote afterloading device is to be used or stored. Areas or rooms used to store remote afterloading devices or source containers housing a source(s) should be secured in accordance with 641-40.55(136C).

1. For medium and high dose-rate devices that will be used in a dedicated treatment room, a description of the following is required:

a. The physical/administrative control of access.

b. The electrical interlock system installed at each entry, including the result of interrupting the interlock when the source is exposed (i.e., whether the source is automatically retracted).

c. The actions required following interruption of the interlock prior to resuming treatment, including confirmation that the interlock must be reset before the afterloading device can be activated.

d. The actions required in case of malfunction of the interlock system. You should confirm that if the system malfunctions, the afterloading device will be locked in the "off" position. Verify that the system will not be used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

e. The restricted area controls (e.g., signs, locks, visible/audible alarms, etc.), including descriptions of signs with their locations, sizes and wording.

f. The method to ensure that whenever the afterloader device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons. You should confirm that no other radiation-producing devices are located in the treatment room, or provide a description of the mechanisms installed to ensure that only one device can be placed in operation at a time.

g. You should confirm that a permanent radiation monitor capable of continuously monitoring the source status will be installed in each dedicated treatment room for high, pulsed and medium dose-rate devices. You should confirm that the proposed monitoring system includes the features described below and commit to performing the specific checks discussed below.

1. The radiation monitor will provide visible notice of an afterloader device malfunction that results in an exposed or partially exposed source. The monitor should be observable by an individual entering the room.

2. The radiation monitor will be equipped with a backup power supply separate from the power supply to the afterloader device. The backup supply may be a battery system.

3. The radiation monitor will be checked with a dedicated check source for proper operation each day before the afterloader device is used. A record of the radiation monitor checks will be maintained for a period three years.

4. If a radiation monitor is inoperable, you will require any individual entering the treatment room to use a survey instrument. The individual will monitor the radiation levels to identify any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The survey instrument will be checked with a dedicated check source for proper operation at the beginning of each day of use.

5. You will promptly repair or replace a radiation monitor that is found to be either inoperable or evidences intermittent problems.

2. For low dose-rate afterloaders that will be used in multiple rooms within a single building, a description of the following is required:

   a. The methods for providing security and surveillance of the patient room.

   b. The restricted area controls (e.g., signs and entrance controls) for the treatment and storage rooms. Include the sign location(s), sizes and wording. Also see section 7.H.

   c. The proposed storage area for the device when not in use.

   d. The method to ensure that whenever the afterloader devices not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

3. To demonstrate compliance with 641-40.26(136C), submit detailed calculations of maximum radiation levels (and dose rates) that will exist in each area (restricted and unrestricted). For programs authorizing the use of a low dose-rate afterloading device in multiple rooms, you should perform the calculations using one or more room configurations, which are representative of those in which patient therapies will be performed. The calculations should include the following:

   a. The expected radiation levels for each area adjacent to the room housing the afterloader device. The radiation levels should consider the most adverse source orientations and maximum source activity used in the device. This includes:
      - maximum source strength
      - combination of sources used for treatment
      - source orientation
      - room size
      - layout
      - treatment time

      You may need to perform several calculations for low dose-rate afterloading devices.

      These calculations should be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirement of 641-40.15(136C) and 40.26(136C).

   b. Specify all parameters used to perform the calculations described above. These parameters should include such factors as distance to each area of concern, the type and thickness of material(s) used in barriers and shields, and the transmission factor

of the barriers or shields, and the maximum source strength. For low dose remote afterloading devices, you should specify the configuration of portable shields, if applicable, used for each set of calculations and the source or source combination.

c. The maximum anticipated workload data, such as maximum "on time" per hour and per week for remote afterloading units that will be used in a dedicated room and occupancy factors used for all adjacent areas. For low dose-rate units which may be used in multiple rooms under varied treatment programs, a profile of your anticipated workload should be provided with representative examples of treatment times, source combinations and occupancy factors for adjacent areas.

d. Calculations to determine the dose received by individuals present in unrestricted areas should consider continuous occupancy (i.e., occupancy factor of one) unless you can make a compelling argument for using a lower value. Calculations to determine the dose received by ancillary staff providing patient care during treatment with low dose-rate afterloading devices should include full details of the occupancy factors used.

e. Results of the calculations are to be expressed in units of rem (or millisieverts) in any one-hour or year, as appropriate.

f. You should demonstrate that the limits specified in 641-40.26(3) will not be exceeded. If your calculations demonstrate compliance with these limits, outline the steps taken to limit exposure to individual members of the public. Options that may be considered include:

    1. Adding shielding to the barrier in question with a corresponding modification of the facility description (if necessary).

    2. Request an exemption and demonstrate how the requirements of 641-40.26(3) will be met. You should demonstrate the need for and the expected duration of operations that will result in an individual dose more than the limits specified in 641-40.26(1). A program to assess and control dose within the 0.5 rem (five mSv) annual limit and procedures followed maintaining the dose as low as is reasonable achievable should be developed and submitted for review.

g. Confirm the implementation of a survey program to demonstrate compliance with 40.26(136C). Submit a description of the program. For medium and high dose-rate devices used in a dedicated treatment room, the program should include requirements for conducting surveys following source replacement and when the device location changes from conditions existing during previous surveys. For low dose-rate afterloading devices, the program should include requirements for conducting surveys following source replacement or loading of any additional sources. Survey programs for low dose-rate afterloading device may include surveys described n Section 10.B. At a minimum, the survey program should be sufficient to confirm the following:

    1. Maximum radiation levels at 10 centimeters from the nearest accessible surface surrounding the main source safe of the afterloader will not exceed one milliroentgen per hour with the source in the shielded position.

    2. Radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure more than the limits of 641-40.15(136C).

    3. Radiation levels in unrestricted areas will not result in a dose to any member of the public more than the limits specified in 641-40.26(136C).

    4. Records of survey results will be maintained for inspection by the IDPH for the duration of the license.

h. You should confirm that conspicuous, durable labels stating "CAUTION RADIOACTIVE MATERIAL," or the equivalent, will be affixed to at least one outer surface of the device as specified in 641-40.63(136C).

10.1. -- OTHER EQUIPMENT AND FACILITIES

Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:

Manufacturer	Model Number	Range
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
LGD Scientific, Inc.	MSB-007	1 - 100000 cpm

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide on survey instrument calibration from the IDPH.

Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing."

ITEM 11. -- RADIATION SAFETY PROGRAM

11.1. - PERSONNEL DOSIMETRY

A. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposures are unexpectedly high or low. This procedure does not apply to backup monitor records (for example, pocket ionization chambers) when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

B. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor. The device will be processed by a contract service on a monthly basis if they exceed 500 millirem per quarter. Those licensees whose employees receive exposures of less than 500 millirem a quarter may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:

- Supporting documentation that confirms that no employee will exceed 500 millirem/ quarter; and;
- proposed frequency of exchange

Note: The exchange frequency should not be changed without IDPH approval.

11.2. - OPERATING AND CALIBRATION PROCEDURES

A. Provide a copy of operating procedures that, at a minimum, include the following commitments:

1. That operating procedures will be provided to appropriate staff and one copy will be maintained at the afterloading device console. Operating procedures may be updated and revised without IDPH approval if such revisions do not relax restrictions or degrade safety.

2. Operating procedures will include steps to ensure that the following requirements are met:

   a. The remote afterloading device(s), console, and treatment or storage room will be secured when unattended.

   b. Only the patient will be in the treatment room during activation of pulsed, medium, and high dose-rate afterloading devices. Written procedures shall be established to insure the source is retracted into the shielded safe before permitting the entry of any visitor(s) into the treatment room
      - if the patient is allowed visitors between treatment fractions with a pulsed dose-rate afterloader, or
      - or during low dose-rate treatments

   The maximum number and length of visits allowed will be charted.

   c. Nursing personnel should follow the authorized user's and Radiation Safety Officer's specific instructions regarding care provided to a patient during treatments performed using low or pulsed dose-rate afterloading devices. If the treatment is to be conducted over a period of several hours if direct patient care will be required, such instructions will be provided to the nursing staff in writing. Nursing personnel will also be provided written instruction on how to maintain radiation exposures ALARA when providing patient care.

   d. Treatment planning computer systems utilizing removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and should be re-labeled) in accordance with the manufacturer's instructions.

   e. Immediately after each use of the afterloading device, a survey of the device and patient will be performed to ensure that the source(s) has (have) been returned to the fully shielded position. To ensure that the source is fully retracted, the survey should include connectors and applicator apparatus, the full length of the catheter guide tube, and the external surface of the device. The patient shall be surveyed over the body surface near the treatment site before removing the patient from the treatment room. For surveys associated with treatments using a medium, high, or pulsed dose-rate afterloading device, the survey instrument should be capable of measuring dose rates of 1 - 1000 millirem per hour. For treatments performed using low dose rate afterloading devices in a patient room, the survey should be performed
      - prior to relocating the patient or portable shielding used during treatment,
      - at the end of treatment or each fraction of treatment, and
      - after any interruption of treatment.

   f. A record of the survey described in Item 2(e) above will be maintained for a period of three years. The record should contain
      - the date of survey
      - identification of the afterloading device (model and serial number)
      - identification of the patient,
      - identification of the instrument used to conduct the survey (make, model, and serial number)
      - a representative background dose rate
      - the survey results, and
      - the initials of the individual performing the survey

   g. A commitment to immediately applicable emergency procedures if the survey specified above in Item 2 (e) indicates that the source is not fully retracted to a shielded position in the device.

h. A commitment to prohibit any treatment procedure for which a de-coupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded container.

i. During all patient treatments using a medium or high dose-rate afterloading device, both the authorized user and either the medical physicist or Radiation Safety Officer should be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech. To satisfy the requirement for ensuring adequate control of the source during patient treatments using a pulsed dose-rate remote afterloading device, you should comply with the requirement described above or submit alternative procedures for IDPH review.

j. During patient treatments using a low dose-rate afterloading device, a device operator trained in your emergency procedures should be physically present at your facility. The medical physicist or Radiation Safety Officer and the authorized user should be available for prompt assistance in the event that a source appears to have de-coupled or becomes jammed in the catheter guide tube. The authorized user and medical physicist or Radiation Safety Officer should be immediately notified of any problems encountered during a treatment. Device operators will follow the instructions of the authorized user and medical physicist/Radiation Safety Officer and implement your emergency procedures as necessary.

B. Confirm, that as a minimum, the following safety checks will be performed and that written, as well as verbal, instruction will be provided to individuals assigned to complete the checks. A description of the method used to perform the following checks should be submitted for review. Procedures should be submitted where indicated:

1. At the beginning of each day of use, the following checks will be performed in accordance with the manufacturer's instructions:

a. For dedicated treatment rooms, the permanent radiation monitor will be checked with a dedicated check source for proper operation.

b. If a dedicated treatment room relies upon a TV monitor to maintain constant observation, the TV monitor will be checked to verify proper operation.

c. Intercom systems installed in dedicated treatment rooms will be checked to verify proper operation.

d. Treatment console operational function check, test of all indicator lamps, other status and operational displays, and, if appropriate, printer test.

e. Source status indicators ("safe" or "unsafe) will be checked using a dedicated check source to verify proper operation. Any additional indicators installed at the treatment console or room entrance must also be checked. The afterloading device may be used to verify proper operation.

f. Electrical interlocks installed at each entrance to a dedicated treatment room for high and medium dose-rate device will be tested for proper operation. See 7.D.1. (d). Records of each test will be maintained for a period of three years and will include the date of the test, the results of the test, and the initials of the individual who performed the test.

g. The mechanical integrity of all applicators, source guide tubes, and connectors to be used shall be determined by visual inspection and/or radiographs. The presence and correct placement of any internal shields and other essential internal components shall be determined.

h. A record of these checks will be maintained for a period of three years. The records should include the date of the check, the results of the check, and the initials of the individual who performed the check.

2. Before use, the following checks must be performed in accordance with the manufacturer's instructions, within the proceeding 30 days:

   a. The afterloading device will be tested to determine the accuracy of source positioning. Source positioning within the catheter guide tube should be accurate to within +/- 1 millimeter of the programmed position. A record of the test will be maintained. It should include the date of the test, the programmed position, the actual position of the source following activation of the device, and the initials of the individual who performed the test. (This record may include the radiograph used to determine source position.) If the source position tolerance noted above (+/- 1 mm) is exceeded, the authorized user and Radiation Safety Officer should be notified before performing patient treatments. You should submit the procedure describing the test. Specify the number of dwell positions used to conduct the test.

   b. Timer accuracy and linearity.

   c. For devices that use a cable and/or wire to transport the source(s), measurement of source guide tubes to confirm the length of one (1) millimeter accuracy.

   d. The backup battery for the remote afterloading device has been tested in accordance with the manufacturer's instructions to verify the capability for emergency source retraction upon power failure. At a minimum, this shall consist of function test with the AC power disconnected.

   e. A record of these checks will be maintained for a period of three years. The record should include the date of the check, the results of the check, and the initials of the individual who performed the check.

C. You should develop and implement procedures governing calibration of the afterloading device. The procedures should be approved by your authorized physicist (s) and should be submitted for review. At a minimum, the calibration procedures should address the following:

1. Calibration measurements of the remote afterloading device source(s) performed by your authorized physicist(s). You should provide information about the individual's experience in the use of dosimetry systems necessary to perform the calibration measurements. You should confirm that the individual(s) performing calibration measurements will complete all measurements and calculations in accordance with the procedures established by your authorized physicist.

2. The method used to determine the exposure rate under specific criteria including the following:
   - distances used for the measurement,
   - whether the measurement is an "in-air" measurement or done using a phantom,
   - configuration of the chamber with respect to the source guide tube and device,
   - scatter factors used to compute the exposure rate.

3. Record maintenance requirements, including a commitment to maintain a record of calibration measurements and associated calculations for a period of three years. The records should include:
   - the manufacturer's name, model number, serial number for both the afterloading device and source

- the manufacturer's name, model number and serial number of the instrument used to measure the output of the afterloading device
- the date that the calibration measurement was performed
- the name of the individual who performed that measurement

The record should also include the output of the device expresses in centigray (rads) per hour or, if appropriate, sieverts (rems) per hour and a comparison of manufacturer's "expected" output value (corrected for decay).

The "expected" and measured output values should be within +/- 5 percent. You should commit to having the results reviewed by their Radiation Safety Officer or medical physicist before performing further patient treatments, if the measured value differs by more than 5 percent of the expected value.

4. A description of the dosimetry system that will be used to perform calibration measurements should be submitted with the procedures. You should also confirm that the dosimetry system (e.g., Farmer chamber, electrometer, etc.) will be calibrated by a laboratory accredited by NIST or AAPM within the previous two years and after any servicing that may have affected system calibration. You should confirm that records of such calibrations will be maintained for inspection.

5. The frequency for calibration measurements should be specified. It is required that calibrations be performed following installation of a new source(s) before patient treatment is resumed, and recommended monthly thereafter.

6. The procedures should include a description of the method to be used to confirm source homogeneity for each source contained in the afterloading device. This may be done by autoradiography, following source replacement but before using the source(s) for patient treatment.

D. Describe the method(s) used for conducting inventories of the source(s) contained in afterloading device(s). To obtain compliance with 641-41.2(46), you should confirm that physical inventories will be conducted quarterly and that records of the inventories will be maintained. To meet this requirement, it is recommended that an autoradiograph be obtained of the source, or set of sources, contained in the afterloading device.

11.3-- <u>EMERGENCY PROCEDURES</u>

A. Submit for review the emergency procedures approved by the authorized user(s) and Radiation Safety Officer or medical physicist. You should confirm that copies of the procedures will be provided to device operators, authorized user(s), and other personnel as necessary. In addition, a copy of the procedure should be posted at the afterloading device console or in a conspicuous location at the treatment area.

B. At a minimum, the procedures should address the following:

1. The procedures are to be implemented if the source cannot be retracted to a fully shielded position in the afterloading device.

2. The actions specified for emergency source removal should consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient.

3. Systematic actions for single or multiple equipment failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios (i.e., source de-coupling versus a jammed source). The procedure should specify situations when surgical intervention may be

necessary and the steps that should be taken in the event that surgical intervention is required.

4. For low dose-rate procedures only, a requirement that the authorized user and the medical physicist or Radiation Safety Officer be notified immediately of any problem requiring implementation of emergency procedures. Include a commitment to post the names, on-duty, and off-duty telephone numbers of these individuals at the operating console of the device. (These individuals are required to be present for pulsed-, high- and medium-dose-rate procedures.)

5. Requirements to restrict and post the treatment area with appropriate signs to minimize the risk of inadvertent exposure of personnel not directly involved in emergency source recovery.

6. The location of source recovery equipment and the equipment that may be necessary for the various equipment failures described in the procedure. At a minimum, emergency equipment should include shielded storage containers; remote handling tools, and, if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

11.4-- MAINTENANCE

A. Confirm that only personnel who are licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services will perform maintenance and repair on the afterloading device. Maintenance and repair includes installation, replacement, relocation or removal of the sealed source or an afterloading device that contains a sealed source. Maintenance and repair also means any adjustment involving any mechanism on the afterloading device, treatment console, or interlocks that could expose the source, reduce the shielding around the source, or affect the source drive controls. (A license authorized for a low dose-rate afterloading device designed as a “mobile” unit may relocate the device for patient treatment if authorized to use the device in multiple rooms.)

   Confirm that a record of any maintenance and repair performed on the afterloading device will be maintained for the duration that the device is in use. The record should include:
   - the date of repair
   - a description of the nature of the maintenance or repair
   - the name of the individual who performed the repair
   - the Agreement State or NRC license number authorizing the individual who performed the repairs

B. Confirm that the following requirements are met for inspection and service of remote afterloading devices.

   1. Each afterloading device will be fully inspected and serviced at intervals not to exceed one year, to ensure proper functioning of the source exposure mechanism. In addition, you should confirm that scheduled service recommended by the manufacturer will be performed in accordance with the manufacturer’s instructions.

   2. Only the manufacturer or other persons specifically licensed by the Commission or an Agreement State will perform inspection and service.

   3. Records of inspection and service will be maintained for the duration of the license. The records will include:
      - the date of the inspection/service
      - the name of the individual who performed the inspection/service

- the Agreement State or NRC license number authorizing the individual to perform inspection/service
- a description of the nature of the inspection/service including a list of the components serviced or replaced
- and the signature of the inspector

C. You may request authorization for an employee trained by the manufacturer to perform maintenance and repair functions. Such authorization should list the employee by name and specify the maintenance and repair functions described in a certificate or letter from the manufacturer of the device documenting the training. A copy of the training certification and an outline of the training should be submitted with the request.

11.5. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

40.10(3) requires annual audits. Submit your proposed audit program. Include the following:

- Name of person or group that will perform the radiation safety audit and the auditors qualifications
- Areas that will be audited
- Checklist or guide that the auditor will use in the course of the audit.
- The proposed enforcement program to ensure deficiencies area corrected

The IDPH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with IDPH rules. Therefore, the consulting service's quality of work and knowledge of IDPH rules should be considered.

12. - WASTE DISPOSAL

You should confirm that the source(s) will be disposed of only by return to an authorized recipient, such as the source/device manufacturer.

ITEM 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.

3. Review 39.4(26) "Financial Assurance and Recordkeeping for Decommissioning." Submit financial assurance as described or provide information that exempts the facility.

ITEM 14, 15 -- CERTIFICATION

The application must be signed by a senior partner, the president, director or chief executive officer. Identify the title of the office held by the individual who signs the application. If the application is for an institution, hospital, or medical center, the director or chief executive officer must sign it.

If the senior partner, president, director, or chief executive officer wishes another person to sign the application, a delegation of authority must be enclosed. The delegation of authority signed by the senior partner, president, director, or chief executive officer should state that the person signing the application

has authority to commit the facility to the conditions of the application and any amendments submitted later.

5. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding to the staff of authorized users. See 641-41.2(4) for the specific requirements. An application for an amendment must be filed on IDPH Form 299-0514 or as a letter and must be signed by the person delegated in Item 14/15. The appropriate fee must be included.

The licensee may not place into effect any amendment until receiving written verification from the IDPH that the amendment has been approved.

6. RENEWAL OF LICENSE

Licenses are issued for a period of Five (5) years. An application for the renewal should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by the IDPH as provided for in paragraph 641-39.4(34). The application for renewal should not reference material that was previously submitted.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

7. IMPLEMENTATION

The information in this regulatory guide is guidance, not requirement. The IDPH reviews each application to ensure that users of by-product material are capable of complying with IDPH's regulations. This guide provides one set of methods approved by the IDPH for meeting the regulations and represents the minimum acceptable standards.

This document is a guide to information required to license a remote afterloading brachytherapy device. If you have a medical use license and wish to add the use of a remote afterloading brachytherapy device, a separate application must be completed.

8. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule. (For example, the routine inspection for a licensee with Irradiated Gemstones would be scheduled four years after the initial inspection.)

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AT MEDICAL INSTITUTIONS ALARA

In addition to 641-41.2(7)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to IDPH Regulatory Guide for Low, Medium, and High Dose-Rate Devices." Submit the signed commitment in section number six of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of 641-41.2(7). Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in section number six of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

   a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC), if applicable, and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far as below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. REVIEW OF PROPOSED USERS AND USES

   a. Review of proposed users and uses

      (1) The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials and methods of use.

(2) When considering the use of by-product material, the RSC will review efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of authority

(1) The RSC will delegate authority for enforcement of an ALARA program to the RSO.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of the ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupation radiation exposure with particular attention to instances in which the investigational levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

TABLE 1

Investigational Levels

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

(3) The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. RADIATION SAFETY OFFICER COMMITMENT

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.

b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
(3) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

4. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

5. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES[1]

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 641-40.100. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the investigational Level I.

b. Personnel doses equal to or greater than Investigation Level I but less than Investigational Level II.

   The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's Form IDPH 588-2834 “Occupational Exposure Record for Monitoring Period” and 588-2833 “Cumulative Occupational Exposure History” or its equivalent.

d. Re-establishment of investigational levels to levels above those listed in Table I.

   In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

   The RSC will review the justification for and must approve all investigational level revisions.

[1] IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

6. SIGNATURE OF CERTIFYING OFFICIAL[1] Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

_____
Signature

_____
Name (Print or type)

_____

[1] The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

Revision	Section	Description
12/26/00	ALL	Reformat text. Changed address for Bureau of Radiological Health
12/17/01	10.D	Rearranged this section to place verbiage regarding area monitors in the section for high and medium dose afterloaders rather than in the low dose afterloader section.
01/18/02	Section 8	Added information concerning inspections.
03/13/03	Section 1.2	Change address for web access to IDPH rules and publications.
07/01/05	ALL	Changed address for the Bureau of Radiological Health
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.
08/08/12	Item 4.1	Updated the requirements for physician authorized user approval.